

Article 18.—UTILIZATION OF UNUSED MEDICATIONS

68-18-1. Transferring unused medications. (a) Each administrator or operator of an adult care home, pharmacist-in-charge of a mail service pharmacy, and administrator of a medical care facility who wants to become a donating entity, as defined in L. 2008, ch. 9, sec. 2 and amendments thereto, shall submit to the board written notification of intent to participate in the unused medications program. The notification shall be submitted on a form approved by the board.

(b) Before the transfer of each unused medication to a qualifying center or clinic, each mail service pharmacy and medical care facility that has become a donating entity as specified in subsection (a) shall perform the following:

(1) Determine the quality and suitability of each unused medication by a pharmacist's verification that the unused medication meets the following requirements:

(A) Can be identified;

(B) is in the manufacturer's sealed container, a pharmacy unit-dose package, or a hermetically sealed tamper evident package from the pharmacy;

(C) has not passed its beyond-use date;

(D) is not a controlled substance;

(E) has not been adulterated; and

(F) is not a medication that can be dispensed only to a patient or resident registered with the drug manufacturer;

(2) remove the name of the patient or resident and all of the patient's or resident's personal identifiers in order to protect confidentiality;

(3) consult with the qualifying center or clinic to determine whether the qualifying center or clinic is willing to accept each unused medication; and

(4) ensure that the qualifying center or clinic has a consulting pharmacist and is registered with the board to accept unused medications.

(c) Before the transfer of each unused medication to a qualifying center or clinic, each adult care home that has become a donating entity as specified in subsection (a) shall meet the requirements specified in paragraphs (b)(2), (3), and (4).

(d) When a donating entity transfers an unused medication to a qualifying center or clinic, the donating entity shall meet the following requirements:

(1) Complete a manifest on a form approved by the board; and

(2) include a copy of the manifest with the unused medications.

(e) Each donating entity shall maintain a copy of the manifest that the donating entity provided to the qualifying center or clinic for at least five years. The donating entity shall also maintain a copy of the manifest that was signed and returned by the qualifying center or clinic for at least five years.

(f) A donating entity shall not transfer an unused medication that can be dispensed only to a patient or resident registered with the drug manufacturer. (Authorized by and implementing L. 2008, ch. 9, §7; effective Jan. 2, 2009.)

68-18-2. Accepting unused medications. (a) Each qualifying center or clinic that elects to participate in the unused medications program shall submit to the board written notification of intent to participate on a form approved by the board.

(b) Each qualifying center or clinic shall maintain all unused medications in a storage unit with controlled access.

(c) After the acceptance of each unused medication from an adult care home that has become a donating entity as specified in K.A.R. 68-18-1(a), each qualifying center or clinic shall perform the following:

(1) Determine the quality and suitability of each unused medication by verification of a pharmacist that the unused medication meets the following requirements, in addition to the requirements of L. 2008, ch. 9, sec. 4 and amendments thereto:

(A) Can be identified; and

(B) is not a medication that can be dispensed only to a patient or resident registered with the drug manufacturer;

(2) ensure that the name of the patient or resident and all of the patient's or resident's personal identifiers have been removed in order to protect confidentiality;

(3) check each unused medication against the manifest to resolve any discrepancies with the donating entity; and

(4) complete the manifest and return a copy of the manifest to the donating entity.

(d) After the acceptance of each unused medication from a mail service pharmacy or a medical care facility that has become a donating entity as specified in K.A.R.

68-18-1(a), each qualifying center or clinic shall perform the following:

(1) Determine the quality and suitability of each unused medication by the verification of a pharmacist or practitioner that the unused medication meets the following requirements, in addition to the requirements of L. 2008, ch. 9, sec. 4 and amendments thereto:

(A) Can be identified; and

(B) is not a medication that can be dispensed only to a patient or resident registered with the drug manufacturer; and

(2) meet all of the requirements specified in paragraphs (c)(2), (3), and (4). (e) Each qualifying center or clinic shall maintain a copy of the manifest that was provided by the donating entity for at least five years. The qualifying center or clinic shall also maintain a copy of the manifest signed and returned to the donating agency for at least five years.

(f) A qualifying center or clinic shall not accept or dispense an unused medication that can be dispensed only to a patient or resident registered with the drug manufacturer.

(Authorized by and implementing L. 2008, ch. 9, §7; effective Jan. 2, 2009.)

68-18-3. Recall of unused medications. (a) If an unused medication is recalled and the qualifying center or clinic does not have the lot number on the label to differentiate between the recalled medications and the nonrecalled medications, all of the unused medications shall be destroyed.

(b) If a donating entity has transferred an unused medication to a qualifying center or clinic, the medication is subsequently recalled, and the donating entity has been notified of the recall, the donating entity shall be responsible for notifying the qualifying center or clinic of the recall.

- (c) Each qualifying center or clinic in possession of any unused medication that is expired, adulterated, or recalled shall make a manifest for and destroy that medication.
- (d) Following the destruction of any unused medications, the manifest shall be signed by the consulting pharmacist and a witness to verify the destruction. Each drug destruction manifest shall be maintained for at least five years. (Authorized by and implementing L. 2008, ch. 9, §7; effective Jan. 2, 2009.)

Chapter 65 - Public Health

Article 16 - Regulation of Pharmacists

65-1668. Utilization of unused medications act; not applicable to certain medications. (a) K.S.A. 65-1668 through 65-1675, and amendments thereto, shall be known and may be cited as the "utilization of unused medications act."

(b) The provisions of the utilization of unused medications act shall not apply to any drug, prescription drug or medication purchased or provided with moneys provided under title XIX of the federal social security act, section 4901 of public law 105-33, 42 U.S.C. 1397aa et seq., and amendments thereto.

History: L. 2008, ch. 9, § 1; Mar. 27.

65-1669. Same; definitions. As used in the utilization of unused medications act:

- (a) "Adult care home" has the same meaning as such term is defined in K.S.A. 39-923, and amendments thereto.
- (b) "Community mental health center" has the same meaning as such term is defined in K.S.A. 75-3307c, and amendments thereto.
- (c) "Donating entities" means adult care homes, mail service pharmacies and medical care facilities who elect to participate in the program.
- (d) "Drug" has the same meaning as such term is defined in K.S.A. 65-1626, and amendments thereto.
- (e) "Federally qualified health center" means a center which meets the requirements for federal funding under 42 U.S.C. section 1396d(1) of the public health service act, and which has been designated as a "federally qualified health center" by the federal government.
- (f) "Indigent health care clinic" has the same meaning as such term is defined in K.S.A. 75-6102, and amendments thereto.
- (g) "Mail service pharmacy" means a licensed Kansas pharmacy located within the state that ships, mails or delivers by any lawful means a lawfully dispensed medication in tamper-resistant packaging to residents of this state or another state.
- (h) "Medical care facility" has the same meaning as such term is defined in K.S.A. 65-425, and amendments thereto.
- (i) "Medically indigent" has the same meaning as such term is defined in K.S.A. 75-6102, and amendments thereto.
- (j) "Medication" means a prescription drug or drug as defined by this section.

- (k) “Mid-level practitioner” has the same meaning as such term is defined in K.S.A. 65-1626, and amendments thereto.
- (l) “Practitioner” has the same meaning as such term is defined in K.S.A. 65-1626, and amendments thereto.
- (m) “Prescription drug” means a drug which may be dispensed only upon prescription of a practitioner or mid-level practitioner authorized by law and which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the federal food, drug and cosmetic act (52 Stat. 1040 (1938), 21 U.S.C.A., section 301).
- (n) “Qualifying center or clinic” means an indigent health care clinic, federally qualified health center or community mental health center.

History: L. 2008, ch. 9, § 2; Mar. 27.

65-1670. Same; duties of the board of pharmacy; duties of qualifying center or clinic.

(a) The board of pharmacy shall establish and implement a program consistent with public health and safety through which unused drugs, other than drugs defined as controlled substances, may be transferred from donating entities that elect to participate in the program for the purpose of distributing the unused medications to Kansas residents who are medically indigent.

(b) A qualifying center or clinic in consultation with a pharmacist shall establish procedures necessary to implement the program established by the utilization of unused medications act.

(c) The state board of pharmacy shall provide technical assistance to entities who may wish to participate in the program.

History: L. 2008, ch. 9, § 3; Mar. 27.

65-1671. Same; criteria for accepting unused medications; dispensing.

The following criteria shall be used in accepting unused medications for use under the utilization of unused medications act:

(a) The medications shall have come from a controlled storage unit of a donating entity;

(b) only medications in their original or pharmacist sealed unit dose packaging or hermetically sealed by the pharmacy in tamper evident packaging, unit of use or sealed, unused injectables shall be accepted and dispensed pursuant to the utilization of unused medications act;

(c) expired medications shall not be accepted;

(d) a medication shall not be accepted or dispensed if the person accepting or dispensing the medication has reason to believe that the medication is adulterated;

(e) no controlled substances shall be accepted; and

(f) subject to the limitation specified in this section, unused medications dispensed for purposes of a medical assistance program or drug product donation program may be accepted and dispensed under the utilization of unused medications act.

History: L. 2008, ch. 9, § 4; Mar. 27.

65-1672. Same; participation; adult care homes; powers and duties of qualifying center or clinic.

(a) Participation in the utilization of unused medications act by residents of adult care homes and donating entities shall be voluntary. Nothing in the utilization of unused medications act shall require any resident of an adult care home or any donating entity to participate in the program.

(b) A qualifying center or clinic which meets the eligibility requirements established in the utilization of unused medications act may:

(1) Dispense medications donated under the utilization of unused medications act to persons who are medically indigent residents of Kansas; and

(2) charge persons receiving donated medications a handling fee not to exceed 200% of the medicaid dispensing fee.

(c) A qualifying center or clinic which meets the eligibility requirements established and authorized by the utilization of unused medications act which accepts donated medications shall:

(1) Comply with all applicable federal and state laws related to the storage and distribution of medications;

(2) inspect all medications prior to dispensing the medications to determine that such medications are not adulterated; and

(3) dispense prescription drugs only pursuant to a prescription issued by a practitioner or mid-level practitioner.

(d) Medications donated under the utilization of unused medications act shall not be resold but are available for transfer to another qualifying center or clinic.

(e) For purposes of the utilization of unused medications act, medications dispensed by qualifying centers or clinics shall not be considered resale of such medications.

History: L. 2008, ch. 9, § 5; Mar. 27.

65-1673. Same; criminal and civil liability under the act.

(a) For matters related only to the lawful donation, acceptance or dispensing of medications under the utilization of unused medications act, the following persons and entities, in compliance with the utilization of unused medications act, in the absence of bad faith or gross negligence, shall not be subject to criminal or civil liability for injury other than death, or loss to person or property, or professional disciplinary action:

(1) The state board of pharmacy;

(2) the department of health and environment;

(3) the department on aging;

(4) any governmental entity or donating entity donating medications under the utilization of unused medications act;

- (5) any qualifying center or clinic that accepts or dispenses medications under the utilization of unused medications act; and
- (6) any qualifying center or clinic that employs a practitioner or midlevel practitioner who accepts or can legally dispense prescription drugs under the utilization of unused medications act and the pharmacy act of the state of Kansas.
- (b) For matters related to the donation, acceptance or dispensing of a medication manufactured by the prescription drug manufacturer that is donated by any entity under the utilization of unused medications act, a prescription drug manufacturer shall not, in the absence of bad faith or gross negligence, be subject to criminal or civil liability for injury other than for death, or loss to person or property including, but not limited to, liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.
- (c) Any person who in good faith donates medications without charge under the utilization of unused medications act, which medications are in compliance with such act at the time donated, shall not be subject to criminal or civil liability arising from any injury or death due to the condition of such medications unless such injury or death is a direct result of the willful, wanton, malicious or intentional misconduct of such person.
- History:** L. 2008, ch. 9, § 6; Mar. 27.

65-1674. Same; rules and regulations; duties of the board of pharmacy.

- (a) The state board of pharmacy shall adopt rules and regulations by December 1, 2008, to implement the utilization of unused medications act. Such rules shall:
- (1) Include standards and procedures for transfer, acceptance and safe storage of donated medications;
 - (2) include standards and procedures for inspecting donated medications to ensure that the medications are in compliance with the utilization of unused medications act and to ensure that, in the professional judgment of a pharmacist, the medications meet all federal and state standards for product integrity;
 - (3) establish standards for acceptance of unused medications from donating entities; and
 - (4) establish, in consultation with the department of health and environment and the department on aging, any additional rules and regulations, and standards and procedures it deems appropriate or necessary to implement the provisions of the utilization of unused medications act.
- (b) In accordance with the rules and regulations and procedures of the program established pursuant to this section, a resident of an adult care home, or the representative or guardian of a resident may donate unused medications, other than prescription drugs defined as controlled substances, for dispensation to medically indigent persons.
- History:** L. 2008, ch. 9, § 7; Mar. 27.

65-1675. Same; duties of the secretary of health and environment; records.

The secretary of health and environment shall maintain records of program participation including the number of donating entities donating medications, recipient locations, the amount of medications received and the number of clients served.

History: L. 2008, ch. 9, § 8; Mar. 27.